

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 0 836 447 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
04.12.2002 Bulletin 2002/49

(51) Int Cl.7: **A61F 2/06**

(86) International application number:
PCT/US96/05842

(21) Application number: **96913197.8**

(87) International publication number:
WO 96/039998 (19.12.1996 Gazette 1996/55)

(22) Date of filing: **26.04.1996**

(54) **PULL BACK SLEEVE SYSTEM WITH COMPRESSION RESISTANT INNER SHAFT**
RÜCKZUG-MANSCHETTENSYSYSTEM MIT DRUCKBESTÄNDIGER INNENWELLE
SYSTEME DE MANCHON A REcul A TIGE INTERIEURE RESISTANT A LA COMPRESSION

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC
NL PT SE

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(30) Priority: **07.06.1995 US 484006**

(43) Date of publication of application:
22.04.1998 Bulletin 1998/17

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(56) References cited:
EP-A- 0 556 940 **WO-A-93/11823**
WO-A-96/13228 **US-A- 4 795 458**

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Description

Field of the Invention

[0001] This invention relates to a stent delivery catheter system, such as the kind used in percutaneous transluminal coronary angioplasty (PTCA) procedures. More particularly, it relates to a stent delivery catheter employing a novel retractable protective sheath and a compression resistant inner shaft.

Background of the Invention

[0002] In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient and advanced through the aorta until the distal end is in the ostium of the desired coronary artery. Using fluoroscopy, a guide wire is then advanced through the guiding catheter and across the site to be treated in the coronary artery. An over the wire (OTW) balloon catheter is advanced over the guide wire to the treatment site. The balloon is then expanded to reopen the artery. The OTW catheter may have a guide wire lumen which is as long as the catheter or it may be a rapid exchange catheter wherein the guide wire lumen is substantially shorter than the catheter. Alternatively, a fixed wire balloon catheter could be used. This device features a guide wire which is affixed to the catheter and cannot be removed.

[0003] In certain known stent delivery catheters, a stent and an optional balloon are positioned at the distal end of the catheter, around a core lumen. The stent and balloon are held down and covered by a sheath or sleeve. When the distal portion is in its desired location of the targeted vessel the sheath or sleeve is pulled back to expose the stent. After the sheath is removed, the stent is free to expand or be expanded. Such stent delivery catheters have had problems with the integrity of the inner core and the outer sheath. In a normal pull back system the friction encountered when pulling the distal sheath off of the stent causes the innermost shaft to compress or accordion and the outermost sheath to elongate. This increases the likelihood of the inner core collapsing and the failure of the device to deploy the stent.

[0004] The prior art includes U.S. Patent No. 4,795,458, which discloses a stent carrying catheter enclosed within a guide catheter. The stent is expandable through temperature change and is loaded onto the end of the catheter, which forms a coil. The stent is deployed by forcing warm saline through the catheter and out through the coiled section of the catheter and over the stent causing it to expand.

[0005] Further prior art includes WO 93/11823, which discloses a pusher-vasoocclusive coil assembly that is advanced through a catheter to a site within a vessel and is manipulated to detach the coil from the assembly via unthreading. The pusher has a distal end that is in-

itially threaded into the proximal end of the coil and the assembly includes a sleeve that is slid over the pusher and holds the coil in place while the distal end of the pusher is threaded out of the coil to detach the coil at the site.

[0006] The present invention is directed toward remedying this collapsing or accordion type failure of the inner core.

Summary of the Invention

[0007] The present invention provides an improved stent delivery catheter according to claim 1 which is delimited over WO 93/11823. The catheter includes a stent disposed on the distal end of the catheter, an inner core, which is flexible and resistant to appreciable compression or accordion, and an outer sheath covering a majority of the inner core, excluding at least a portion of the distal end of the inner core. The catheter further comprises a retractable distal sheath which covers at least a portion of the stent and a portion of the distal end of the inner core and a retracting means for retraction the distal sheath to release the stent.

[0008] Other objects, features, and characteristics of the present invention, as well as the methods of operation and functions of the related elements of the structure, and the combination of parts and economics of manufacture, will become more apparent upon consideration of the following description with reference to the accompanying drawings, all of which form a part of this specification.

Brief Description of the Figures

[0009]

Figure 1 shows a side view of a catheter according to the invention including a cross-sectional view of the distal portion thereof.

Figure 2 shows a partial cut away view of a distal portion of a catheter according to the invention.

Figure 3 shows a side view of the proximal end of a catheter according to the invention showing the manifold portion thereof.

Figures 4a-4d show side views of optional contour patterns for the retractable distal sheath of the invention.

Detailed Description of the Invention

[0010] In Figure 1 there is shown a cross-section of the distal portion of a specific embodiment of a stent delivery catheter generally designated as 10. The device generally comprises an outer sheath 20 which covers the majority of the catheter excluding a portion of the distal end of the catheter. This sheath 20 is characterized by a low friction coefficient and high flexibility, and preferably is comprised of a polyolefinic ionomer mate-

rial, such as a single layer Surlyn™ sheath. The outer sheath 20 surrounds an inner core 40 which extends to the distal tip 12 of the catheter. The inner core is preferably a spring coil 40, the manufacture of which is well known in the art, and is fashioned to be both flexible when navigated through body lumens and rigid when being pulled back upon itself during stent release. The spring coil may be made from a variety of material, including stainless steel, Elgiloy™, Nitinol™, Kevlar™ or other metals and structural plastics. Preferably, it is made from stainless steel. The present invention further comprises a retractable distal sheath 14 covering a stent 18, which is loaded around the distal end of the inner core 40, and a retracting member 41, which is connected to the retractable distal sheath 14 and allows the physician to retract the distal sheath 14 from the proximal end of the catheter. The retractable sheath 14 may be flexible or rigid, and is generally used to protect stent 18 and the vessel wall and/or to hold a self-expanding stent in the delivery configuration. The distal sheath 14 and the method for making it are discussed further below. The retracting member 41 may be a rod, a tube, a pull back wire or the like, but is preferably a wire. The retracting member 41 extends proximally through the outer sheath 20, preferably through a retracting member lumen 80, such as a tube preferably made from high density polyethylene (HDPE), but which could also be made from low density polyethylene (LDPE), polyimide, Teflon™ or other lubricious shaft material. In the preferred embodiment, the retracting member lumen 80 extends longitudinally under the outer sheath 20, and houses the pull back wire 41. The retracting member lumen 80 that houses the pull back wire 41 may also carry flushing fluid for purging and cleaning the catheter at the distal end. Retracting member 41 exits the retracting member lumen 80 at exit hole 90, and continues distally to where it is attached to the distal sheath at point 21. The invention additionally comprises a proximal sheath 16 which covers the exposed area between the outer sheath 20 and the distal sheath 14, serving to protect the inner core 40 and the retracting member 41 in this area. The proximal sheath 16 is adhered to the proximal end of the distal sheath 14 and slidably overlaps the distal end of the outer sheath 20. As the distal sheath 14 is retracted, the proximal sheath 16 is forced back, sliding over the outer sheath 20 giving the distal sheath room to retract. The distance between the proximal end of the distal sheath 14 and exit hole 90 should preferably be far enough apart to allow complete release of the stent. The distal sheath 14 and the proximal sheath 16 may be two separate sheaths adhered to one another, or they may be combined to form a continuous sheath. Finally, a stiffening wire 60, preferably made from stainless steel, but which could also be made from Nitinol™ or Elgiloy™, may also be incorporated longitudinally along the axis of the catheter 10 for extra stability and control.

[0011] Figure 2 shows the layers of the catheter ex-

cluding the distal portion of the outer sheath 20, the distal and proximal sheaths and the stent. As shown, the stiffening wire 60 and the retracting member lumen 80, which are positioned longitudinally along the catheter, may be truncated prior to the flexible distal tip. The truncated portion 28 may be terminated at the end of the outer sheath 20 or extend into the gap between the distal end of the outer sheath 20 and the proximal end of the distal sheath 14, as shown in Fig. 1. The retracting member 41 extends out through the truncated lumen 28 connecting with the distal sheath 14.

[0012] In the preferred embodiment, the distal sheath 14 is connected via a short section of hypotube 22, configured as an annular ring, to the pull back wire 41. The proximal end of the distal sheath 14 is adhered to the annular ring 22 and the pull back wire 10 is connected, preferably welded, to the inside of the annular ring 22. Proximal to the placement of the stent 18 is a stopper 24. The stopper 24 is usually a piece of tubing attached at position 23 to the inner core, and is used to prevent the stent 18 from moving proximally when the distal sheath 14 is pulled back over the stent 18.

[0013] The proximal portion of the catheter, as shown in Figure 3, comprises of a manifold system 27 which includes a sliding member 26 slidably integrated between the distal end of the manifold and the proximal Luer fitting 30. It is connected to the pull back wire 41 by a weld, insert mold or other connection means. By sliding the sliding member 26 of the manifold 27, distal to proximal, the distal sheath 14 is retracted exposing the stent 18. The manifold 27 may further comprise a hydrating luer 32, which is located on the distal end of the manifold 27 and is used to hydrate the distal tip 12.

[0014] The inner core 40 is a non-compressible inner shaft that resists collapse or accordion type failure during the retraction of the distal sheath 14. In the preferred embodiment, a spring coil, most preferably a 6-fillar spring coil, is utilized for the inner core of the delivery device. A spring coil 40 such as used in the present invention provides both flexibility during placement and rigidity during distal sheath retraction. The spring coil 40 allows the delivery system to deploy the stent 18 despite the amount of friction encountered at the distal end resulting from the use of a self expanding stent 18. As the wire 41 is pulled back to expose the self expanding stent 18, the spring coil 40 will collapse slightly upon itself until the excess pitch has been taken up. Once this has happened, the spring coil 40 behaves as a rigid solid structure and therefore will not accordion, providing enough structural support for the distal sheath 14 to be pulled back and expose the self expanding stent 18.

[0015] To prepare the stent delivery catheter 10 the stent 18 is compressed and loaded on the distal end of the inner core 40 inside of the distal sheath 14. The stent 18 is surrounded by protective distal sheath 14. The distal sheath remains covering the underlying stent during the placement of the stent 18 by the delivery catheter 10 through the patient's vasculature. During the place-

ment of the stent, protective distal sheath 14 protects the patient's vasculature from the stent 18. When it is time to expand the stent 18 into an enlarged diameter form and secure the stent in a patient's vasculature, the distal sheath 14 is retracted from over stent 18 by sliding the sliding member 26 proximally. As the sliding member is pulled back the distal sheath 14 starts to retract. Once the stent 18 is dragged slightly back by the retracting distal sheath and is butted up against the stopper 24, the stent 18 expands fully as the distal sheath 14 continues to be pulled back. Preferably the stent is self-expanding, such as a well known Nitinol™ stent, or it may be expanded by means of an optional internal balloon (not shown) positioned under the stent on the distal end of the inner core 40, as is well known in the art. Once the sheath 14 is fully retracted the optional placement balloon would be inflated through its inflation lumen (not shown) to deploy the stent. After the stent is expanded and in place, the catheter is withdrawn.

[0016] The stent deployment catheter preferably incorporates a distal sheath material covering the stent with the following characteristics: low coefficient of friction to slide over the stent, which may comprise collagen material coating or bare metal, radial strength in order to hold down the self expanding stent and high flexibility to maneuver through torturous vasculature. Sheaths comprising tetrafluoroethylene fluorocarbon polymers (TFEF) or fluorinated ethylene-propylene resins (FEP), such as Teflon™, have been found by the inventor to have the least amount of friction when dragged against the stent and inner core, while providing adequate radial strength to hold the stent in place. However, the TFEF/FEP sheaths have thick walls and make the distal tip too stiff for use in the peripheral anatomy. The present invention contemplates using TFEF/FEP sheaths as the distal sheath, or both the distal sheath and the proximal sheath, of the stent deployment catheter and a new method of making the thick TFEF/FEP sheaths more flexible for use in a tortuous anatomy.

[0017] In making the desired distal sheath, a standard piece of Teflon™ tubing is placed on a mandrel just slightly smaller than the tubing's inner diameter. Using a coil winder, a wire coil is wound directly over the tubing advancing from one end to the other end, noting the pitch and tension of the wire as the coil is laid on top of the Teflon™ tubing. The wire chosen can be either a round cross section or a rectangular cross section, preferably round with a diameter between 0.0127 cm and 0.0381 cm (0.005 inch - 0.015 inch). Heat is applied circumferentially to the coil wound tubing, at about 375° C - 450° C, preferably 420° C. The tubing is then allowed to cool to approximately room temperature and the spring coil and the mandrel are removed from the tubing leaving a contoured tube. The coil winder used to create the contoured surface may be wound to produce a variety of contour patterns. Figures 4a-4d illustrate possible configurations. The amount of flexibility can be controlled by varying the amount of tension on the wire, the

size of the wire, the wire profile, and the pitch of the wire. Preferably, a pitch of 0.0254 cm to 0.1905 cm (0.01 inch - 0.075 inch) is utilized.

[0018] This type of heat method provides a contoured surface on the Teflon™ sheath which results in a measurably improved retractable sheath having increased flexibility and sufficient strength. During heating, the tension from the hot wire leaves grooves in the softened tubing which allow the tubing to be more flexible. The resultant increase in flexibility is by approximately seven times when compared to the original piece of tubing, while still providing enough radial strength to hold down the stent as well as providing the needed lubricity to remove the sheath from the stent. While fluorinated polymers are preferred, any thermoformable polymer may be employed.

[0019] The contouring process may also be used to provide flexible shafts for other medical devices such as balloon catheters or infusion catheters, or for any other devices in which a flexible shaft is needed. In an infusion catheter, flexibility could be provided by contouring the distal end of the device. In a balloon catheter, the contouring could be used on either the inflation lumen or guidewire lumen as it would provide for fluid containment while providing flexibility.

Claims

1. A stent delivery system comprising:

- an inner core (40) having proximal and distal ends;
- a stent (18) concentrically arranged around the inner core (40) near the distal end;
- an outer sheath (20) concentrically arranged around the inner core (40);
- a retractable distal sheath (14, 16) surrounding at least a portion of the stent (18), and retracting means being connected to the retractable distal sheath (14, 16) for retracting the retractable distal sheath (14, 16) proximally relative to the outer sheath (20) such that the retracting means moves axially with respect to the outer sheath (20),
- whereby when the retracting means is retracted the retractable distal sheath (14, 16) is retracted freeing the stent (18) for delivery, characterized in that
- the outer sheath (20) being positioned along the inner core (40) proximal to the stent (18), the retractable distal sheath (14, 16) being concentrically arranged around the inner core (40) toward the distal end thereof, and being concentrically arranged around the inner core (40) toward the distal end thereof and substantially distal to the outer sheath (20), such that the retractable distal sheath (14, 16) is slidably mov-

- able over the inner core (40) and relative to the outer sheath (20), and the retracting means is extending from the proximal end of the stent delivery system toward the distal end within the outer sheath (20). 5
2. The stent delivery system as in claim 1, wherein the retractable distal sheath (14, 16) overlaps a portion of the distal end of the outer sheath (20). 10
 3. The stent delivery system as in claim 1 or 2, wherein the retracting means comprises a pull back wire (41) attached to the retractable distal sheath (14, 16), the pull back wire (41) being longitudinally movable, and wherein the inner core comprises a spring coil. 15
 4. The stent delivery system as in claim 3, further comprising an annular ring (22), wherein the pull back wire (41) is attached to the annular ring (22) and wherein the retractable distal sheath (14, 16) is adhered to the annular ring (22) allowing the pull back wire (41) to retract the retractable distal sheath (14, 16). 20
 5. The stent delivery system as in claim 4, wherein the annular ring (22) is attached to the proximal end of the distal sheath (14). 25
 6. The stent delivery system as in claim 4 or 5, further comprising a stopper (24) attached to the inner core (40) and positioned to prevent the stent (18) from moving proximally as the retractable distal sheath (14, 16) is retracted to expose the stent (18). 30
 7. The stent delivery system as in claim 6, further comprising a pull back wire lumen (80) which partially encloses the pull back wire (41) and is at least partially covered by the outer sheath (20). 35
 8. The stent delivery system as in claim 7, further comprising a stiffening wire (60) having proximal and distal ends positioned longitudinally along the inner core (40). 40
 9. The stent delivery system as in claim 8, wherein the distal end of the stiffening wire (60) and the distal end of the pull back wire lumen (80) are truncated prior to the annular ring (22). 45
 10. The stent delivery system according to one of the claims 1 to 5, wherein the retractable distal sheath (14, 16) comprises a proximal sheath (16) having proximal and distal ends, the proximal end of the proximal sheath (16) being in contact with the distal end of the outer sheath (20), and a distal sheath (14) having proximal and distal ends, the distal end of the proximal sheath (16) being connected to the proximal end of the distal sheath (14). 50
 11. The stent delivery system according to claim 10, wherein the proximal end of the proximal sheath (16) overlaps the distal end of the outer sheath (20). 55
 12. The stent delivery system as in claim 10 or 11, further comprising a manifold (27) at the proximal end of the stent delivery system, the manifold (27) comprising a sliding member (26) which is connected to the pull back wire (41) and acts to retract said pull back wire (41).
 13. The stent delivery system as in claim 12, wherein the outer sheath (20) comprises polyolefinic ionomer material.
 14. The stent delivery system as in claim 13, wherein the retractable distal sheath is made of material which comprises tetrafluoroethylene Fluorocarbon polymers or fluorinated ethylene-propylene resins.
 15. The stent delivery system as in claim 14, wherein the distal sheath comprises a contoured pattern of grooves.
 16. The stent delivery system as in claim 15, further comprising a hydrating luer located on the manifold, a distal tip located at the distal end of the catheter and a communication means between the hydrating luer and the distal tip which allows for hydrating the distal tip from the hydrating luer.
 17. The stent delivery system as in one of the preceding claims, wherein the inner core extends substantially the full length of the stent delivery system and is made from a wire coil with a predetermined pitch such that it is flexible in an uncompressed state, and will become rigid when compressed, whereby when the retracting means is retracted to free the stent for delivery, the retractable distal sheath (14, 16) is retracted, causing the wire coil to compress, making the wire coil substantially rigid, preventing the inner core from collapsing.
 18. The stent delivery system as in claim 13, further comprising a pull back wire lumen (80) through which the pull back wire (41) extends, the pull back wire (41) having a distal portion which extends out of the pull back wire lumen (80) being in fluid communication with a hydrating luer (32) attached to the manifold (27).
 19. The stent delivery system according to one of the preceding claims, wherein the inner core (40) is substantially incompressible.

Patentansprüche

1. Stentzuführsystem, mit:

5 einem inneren Kern (40) mit proximalen und distalen Enden;
 einem Stent (18), der nahe an dem distalen Ende konzentrisch um den inneren Kern (40) herum angeordnet ist;
 10 einer äußeren Hülle (20), die konzentrisch um den inneren Kern (40) herum angeordnet ist;
 einer zurückziehbaren distalen Hülle (14, 16), die zumindest einen Abschnitt des Stents (18) umgibt, und
 15 ein mit der zurückziehbaren distalen Hülle (14, 16) verbundenes Rückzugsmittel, um die zurückziehbare distale Hülle (14, 16) proximal relativ zu der äußeren Hülle (20) derart zurückzuziehen, daß sich das Rückzugsmittel axial in bezug auf die äußere Hülle (20) bewegt,
 20 wobei dann, wenn das Rückzugsmittel zurückgezogen wird, die zurückziehbare distale Hülle (14, 16) zurückgezogen wird und den Stent (18) zwecks Zuführung freigibt, **dadurch gekennzeichnet, daß**
 25 die äußere Hülle (20) längs des inneren Kerns proximal zu dem Stent (18) positioniert ist, die zurückziehbare distale Hülle (14, 16) konzentrisch um den inneren Kern (40) herum in Richtung zu dem distalen Ende desselben angeordnet ist und konzentrisch um den inneren Kern (40) herum in Richtung zu dem distalen Ende desselben angeordnet ist und im wesentlichen distal derart zu der äußeren Hülle (20) ist, daß die zurückziehbare distale Hülle (14, 16) gleitfähig über den inneren Kern (40) und relativ zu der äußeren Hülle (20) bewegbar ist, und
 30 sich das Rückzugsmittel von dem proximalen Ende des Stentzuführsystems in Richtung zu dem distalen Ende innerhalb der äußeren Hülle (20) erstreckt.

2. Stentzuführsystem nach Anspruch 1, wobei die zurückziehbare distale Hülle (14, 16) einen Abschnitt des distalen Endes der äußeren Hülle (20) überdeckt. 45
3. Stentzuführsystem nach Anspruch 1 oder 2, wobei das Rückzugsmittel einen Rückzugsdraht (41) umfaßt, der an der zurückziehbaren distalen Hülle (14, 16) befestigt ist, wobei der Rückzugsdraht (41) in Längsrichtung bewegbar ist, und wobei der innere Kern eine Federwindung umfaßt. 50
4. Stentzuführsystem nach Anspruch 3, ferner mit einem Rundring (22), wobei der Rückzugsdraht (41) an dem Rundring (22) befestigt ist, und wobei die 55

zurückziehbare distale Hülle (14, 16) mit dem Rundring (22) verklebt ist, wodurch der Rückzugsdraht (41) die zurückziehbare distale Hülle (14, 16) zurückziehen kann.

5. Stentzuführsystem nach Anspruch 4, wobei der Rundring (22) an dem proximalen Ende der distalen Hülle (14) befestigt ist.
6. Stentzuführsystem nach Anspruch 4 oder 5, ferner mit einem Anschlag (24), der an dem inneren Kern (40) befestigt ist und so positioniert ist, daß er den Stent (18) sich nicht proximal bewegen läßt, wenn die zurückziehbare distale Hülle (14, 16) zurückgezogen wird, um den Stent (18) freizulegen.
7. Stentzuführsystem nach Anspruch 6, ferner mit einem Rückzugsdrahtlumen (80), das den Rückzugsdraht (41) zum Teil umschließt und zumindest zum Teil von der äußeren Hülle (20) bedeckt ist.
8. Stentzuführsystem nach Anspruch 7, ferner mit einem Versteifungsdraht (60) mit proximalen und distalen Enden, die in Längsrichtung längs des inneren Kerns (40) positioniert sind.
9. Stentzuführsystem nach Anspruch 8, wobei das distale Ende des Versteifungsdrahtes (60) und das distale Ende des Rückzugsdrahtlumens (80) vor dem Rundring (22) schräg abgeschnitten sind.
10. Stentzuführsystem nach einem der Ansprüche 1 bis 5, wobei die zurückziehbare distale Hülle (14, 16) eine proximale Hülle (16) mit proximalen und distalen Enden umfaßt, wobei das proximale Ende der proximalen Hülle (16) mit dem distalen Ende der äußeren Hülle (20) in Kontakt steht, sowie eine distale Hülle (14) mit proximalen und distalen Enden, wobei das distale Ende der proximalen Hülle (16) mit dem proximalen Ende der distalen Hülle (14) verbunden ist.
11. Stentzuführsystem nach Anspruch 10, wobei das proximale Ende der proximalen Hülle (16) das distale Ende der äußeren Hülle (20) überdeckt.
12. Stentzuführsystem nach Anspruch 10 oder 11, des weiteren mit einem Verteiler (27) an dem proximalen Ende des Stentzuführsystems, wobei der Verteiler (27) ein Gleitelement (26) umfaßt, das mit dem Rückzugsdraht (41) verbunden ist und so wirkt, daß es den Rückzugsdraht (41) zurückzieht.
13. Stentzuführsystem nach Anspruch 12, wobei die äußere Hülle (20) polyolefinisches Ionomerumaterial umfaßt.
14. Stentzuführsystem nach Anspruch 13, wobei die

- zurückziehbare distale Hülle aus Material besteht, das Tetrafluorethylen-Fluorkohlenstoffpolymere oder Fluorethylenpropylenharze umfaßt.
15. Stentzuführsystem nach Anspruch 14, wobei die distale Hülle ein profiliertes Nutenmuster umfaßt. 5
16. Stentzuführsystem nach Anspruch 15, ferner mit einer an dem Verteiler angeordneten Luer-Wasserversorgungsspritze, einer an dem distalen Ende des Katheters angeordneten distalen Spitze und einem Verbindungsmittel zwischen der Luer-Wasserversorgungsspritze und der distalen Spitze, durch das die distale Spitze von der Luer-Spritze aus mit Wasser versorgt werden kann. 10 15
17. Stentzuführsystem nach einem der vorhergehenden Ansprüche, wobei sich der innere Kern im wesentlichen über die volle Länge des Stentzuführsystems erstreckt und aus einer Federwindung mit einer vorbestimmten Steigung besteht, so daß diese in einem nicht zusammengedrückten Zustand flexibel ist und beim Zusammendrücken starr wird, wodurch dann, wenn das Rückzugsmittel zurückgezogen wird, um den Stent zwecks Zuführung freizugeben, die zurückziehbare distale Hülle (14, 16) zurückgezogen wird, wodurch die Federwindung zusammengedrückt wird und dadurch die Federwindung im wesentlichen versteift, damit der innere Kern nicht zusammenfallen kann. 20 25 30
18. Stentzuführsystem nach Anspruch 13, des weiteren mit einem Rückzugsdrahtlumen (80), durch das hindurch sich der Rückzugsdraht (41) erstreckt, wobei der Rückzugsdraht (41) einen distalen Abschnitt aufweist, der aus dem Rückzugsdrahtlumen (80) herausragt, das in Fluidverbindung mit einer an dem Verteiler (27) befestigten Luer-Wasserversorgungsspritze (32) steht. 35 40
19. Stentzuführsystem nach einem der vorhergehenden Ansprüche, wobei der innere Kern (40) im wesentlichen unkomprimierbar ist. 45

Revendications

1. Système de mise en place d'extenseur endovasculaire comprenant :

une âme interne (40) présentant des extrémités proximale et distale ;
 un extenseur endovasculaire (18) disposé concentriquement autour de l'âme interne (40), à proximité de l'extrémité distale ;
 une gaine externe (20) disposée concentriquement autour de l'âme interne (40) ;
 une gaine distale rétractable (14, 16) entourant

au moins une partie de l'extenseur (18), et des moyens rétracteurs qui sont raccordés à la gaine distale rétractable (14, 16) pour rétracter celle-ci dans une position proximale relativement à la gaine externe (20), de sorte que les moyens rétracteurs se déplacent axialement par rapport à la gaine externe (20), grâce à quoi, lorsque les moyens rétracteurs sont rétractés, la gaine distale rétractable (14, 16) est rétractée en libérant l'extenseur (18) en vue de sa mise en place, **caractérisé en ce que** la gaine externe (20) est positionnée au long de l'âme interne (40), à proximité de l'extenseur (18), la gaine distale rétractable (14, 16) est disposée concentriquement autour de l'âme interne (40) vers l'extrémité distale de celle-ci, et de façon sensiblement distale à la gaine externe (20), de sorte que la gaine distale rétractable (14, 16) peut être déplacée, par coulissement, par dessus l'âme interne (40) et par rapport à la gaine externe (20), et les moyens rétracteurs s'étendent, de l'extrémité proximale du système de mise en place d'extenseur, vers l'extrémité distale, à l'intérieur de la gaine externe (20).

2. Système de mise en place d'extenseur selon la revendication 1, dans lequel la gaine distale rétractable (14, 16) chevauche une partie de l'extrémité distale de la gaine externe (20).
3. Système de mise en place d'extenseur selon la revendication 1 ou 2, dans lequel les moyens rétracteurs comprennent un fil métallique de rappel (41) fixé à la gaine distale rétractable (14, 16), le fil métallique de rappel (41) pouvant être déplacé longitudinalement, et dans lequel l'âme interne comprend un ressort hélicoïdal.
4. Système de mise en place d'extenseur selon la revendication 3, comprenant, en outre, une bague annulaire (22), dans lequel le fil métallique de rappel (41) est fixé à la bague annulaire (22) et dans lequel la gaine distale rétractable (14, 16) adhère à la bague annulaire (22) en permettant au fil métallique de rappel (41) de rétracter la gaine distale rétractable (14, 16).
5. Système de mise en place d'extenseur selon la revendication 4, dans lequel la bague annulaire (22) est fixée à l'extrémité proximale de la gaine distale (14).
6. Système de mise en place d'extenseur selon la revendication 4 ou 5, comprenant, en outre, une bûtte (24) fixée à l'âme interne (40) et positionnée de

- manière à empêcher l'extenseur (18) de se déplacer de façon proximale lorsque la gaine distale rétractable (14, 16) est rétractée afin de dégager l'extenseur (18).
7. Système de mise en place d'extenseur selon la revendication 6, comprenant, en outre, une lumière de fil métallique de rappel (80) qui entoure partiellement le fil métallique de rappel (41) et qui est recouverte au moins partiellement par la gaine externe (20). 5
 8. Système de mise en place d'extenseur selon la revendication 7, comprenant, en outre, un fil métallique de raidissement (60) présentant des extrémités proximale et distale qui sont positionnées longitudinalement le long de l'âme interne (40). 10
 9. Système de mise en place d'extenseur selon la revendication 8, dans lequel l'extrémité distale du fil métallique de raidissement (60) et l'extrémité distale de la lumière de fil métallique de rappel (80) sont tronquées avant la bague annulaire (22). 15
 10. Système de mise en place d'extenseur selon l'une des revendications 1 à 5, dans lequel la gaine distale rétractable (14, 16) comprend une gaine proximale (16) présentant des extrémités proximale et distale, l'extrémité proximale de la gaine proximale (16) étant au contact de l'extrémité distale de la gaine externe (20), et une gaine distale (14) présentant des extrémités proximale et distale, l'extrémité distale de la gaine proximale (16) étant raccordée à l'extrémité proximale de la gaine distale (14). 20
 11. Système de mise en place d'extenseur selon la revendication 10, dans lequel l'extrémité distale de la gaine proximale (16) chevauche l'extrémité distale de la gaine externe (20). 25
 12. Système de mise en place d'extenseur selon la revendication 10 ou 11, comprenant, en outre, une tubulure (27) à l'extrémité proximale du système de mise en place d'extenseur, la tubulure (27) comprenant un organe coulissant (26) qui est raccordé au fil métallique de rappel (41) et qui agit pour rétracter ledit fil métallique de rappel (41). 30
 13. Système de mise en place d'extenseur selon la revendication 12, dans lequel la gaine externe (20) comprend un matériau d'ionomère polyoléfinique. 35
 14. Système de mise en place d'extenseur selon la revendication 13, dans lequel la gaine distale rétractable est réalisée à partir d'un matériau qui comprend des polymères de tétrafluoroéthylène ou des résines éthylène-propylène fluorées. 40
 15. Système de mise en place d'extenseur selon la revendication 14, dans lequel la gaine distale comprend une configuration profilée de gorges. 45
 16. Système de mise en place d'extenseur selon la revendication 15, comprenant, en outre, un "luer" hydratant situé sur la tubulure, un bout distal situé à l'extrémité distale du cathéter et un moyen de communication entre le "luer" hydratant et le bout distal, qui permet d'hydrater le bout distal à partir du "luer" hydratant. 50
 17. Système de mise en place d'extenseur selon l'une des revendications précédentes, dans lequel l'âme interne s'étend sensiblement sur toute la longueur du système de mise en place d'extenseur et est réalisée à partir d'un fil hélicoïdal présentant un pas prédéterminé tel qu'elle est flexible à l'état non comprimé et rigide à l'état comprimé, grâce à quoi, lorsque les moyens rétracteurs sont rétractés de façon à libérer l'extenseur en vue de sa mise en place, la gaine distale rétractable (14, 16) est rétractée, provoquant la compression du fil hélicoïdal et rendant le fil hélicoïdal sensiblement rigide, ce qui empêche l'affaissement de l'âme interne. 55
 18. Système de mise en place d'extenseur selon la revendication 13, comprenant, en outre, une lumière de fil métallique de rappel (80) à travers laquelle s'étend le fil métallique de rappel (41), le fil métallique de rappel (41) comportant une partie distale qui s'étend en dehors de la lumière de fil métallique de rappel (80) en communication de fluide avec un "luer" hydratant (32) fixé à la tubulure (27).
 19. Système de mise en place d'extenseur selon l'une des revendications précédentes, dans lequel l'âme interne (40) est sensiblement incompressible.

Fig. 1

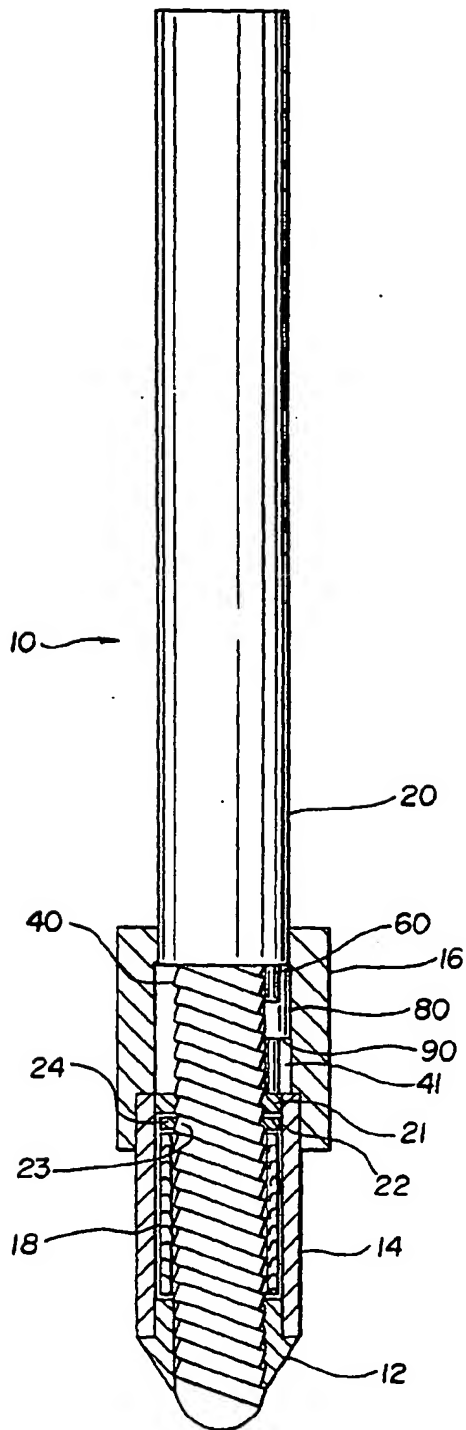


Fig. 2

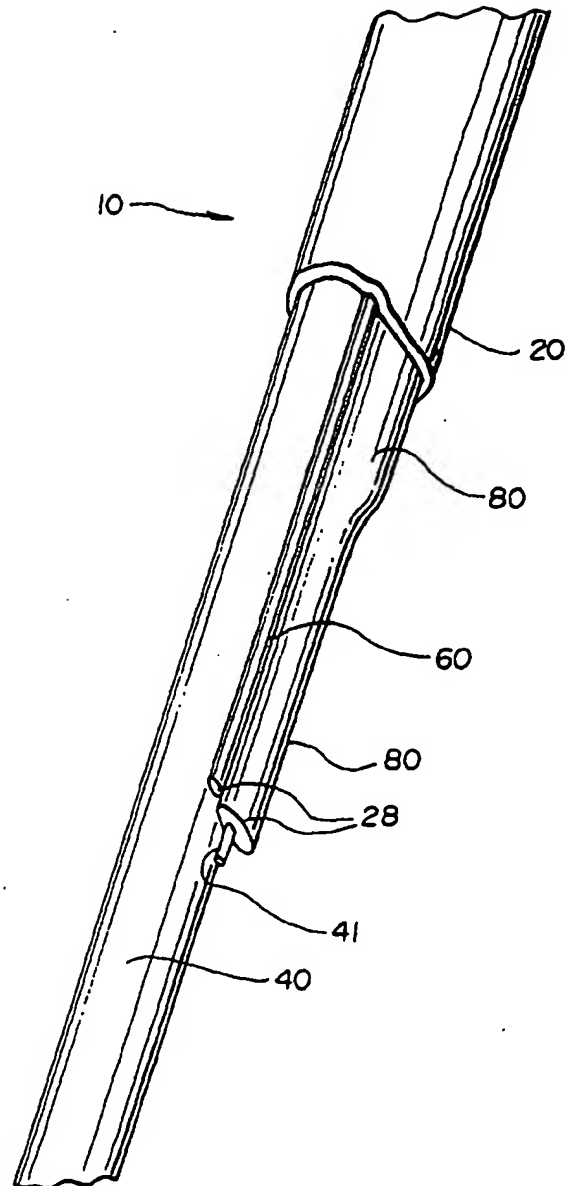


Fig. 3

